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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,033	10/22/2001	Patrick C. Kung	YALE-025/02US	9303

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

MAIL DATE DELIVERY MODE

07/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/830,033

Applicant(s)

KUNG ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83,84,87 and 88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83,84,87,88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/05/2007 has been entered.

Status of Claims

Claims 83,84,87,88 are pending.

Claim Rejections - 35 USC § 103.

Claims 83,84,87,88 are rejected under 35 U.S.C. 103(a) as obvious over Khwaja et al (US Patent 6113907) in view of Bevilacqua (US patent 6692916).

Khwaja et al is applied as discussed in the previous Office actions.

The reference does not teach use of genomic based bioassays but teaches that use of bioassays is necessary for ensuring quality of a botanical product.

Complex plant materials and extracts exist which have potent, but relatively unpredictable, medicinal properties. These materials are, for the most part, useless in a clinical setting because of the inherent

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risks involved with treating patients with poorly characterized materials which have no established batch consistency and which may differ widely in composition. Accordingly, there is a need to provide methods for standardizing such complex botanical materials

The use of gene arrays for fingerprinting and content control is well known in the art. Thus, Bevilacqua (US patent 6692916) teach that

There has been increasing interest in herbal drugs or nutraceuticals. These compounds are grown and collected from around the world, and consequently the compounds are subject to regional and temporal differences in collection and preparation that are difficult to control. It is frequently the case that one batch of a nutraceutical may be effective, there is no assurance that a second batch will be effective.

(col. 1, lines 40-50).

The reference teaches use of gene-based assays using a calibrated profile data set derived from a data set having a plurality of members, each member being a quantitative measure of the amount of a subject's RNA or protein as distinct constituents in a panel of constituents. See claims and col. ... Selected baseline profile data sets may be also be used as a standard by which to judge manufacturing lots in terms of efficacy, toxicity, etc. Where the effect of a therapeutic agent is being measured, the baseline data set may correspond to gene expression profiles taken before administration of the agent. Where quality control for a newly manufactured product is being determined, the baseline data set may correspond with a gold standard for that product. However, any suitable normalization techniques may be employed. For example, an average baseline profile data set is obtained from authentic material of a naturally grown herbal nutraceutical and compared over time and over different lots in order to demonstrate consistency, or lack of consistency, in lots of compounds prepared for release. See col. 21. Each member of the first calibrated profile data set is a function of a corresponding member of the first profile data set and a corresponding member of a first baseline profile data set for the panel, and (ii) each member of the

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second calibrated profile data set is a function of a corresponding member of the second profile data set and a corresponding member of a second baseline profile data set for the panel. Col. 4.

It will be *prima facie* obvious to one skilled in the art at the time the invention was made to be motivated to use genomic-based assay of Bevilacqua in the method of Khwaja et al to provide control and standardization of the herbal preparations samples in the method of Khwaja. One of ordinary skill in the art would not be confined by the particular assays taught in in the method of Khwaja and will have reasonable expectation of success that genomic-based assays will be equally effective.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571)272-0735 . The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Borin, Ph.D.

Primary Examiner

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A handwritten signature in black ink, appearing to read 'Michael Borin', with a long horizontal stroke extending to the right.

mlb